EPA REGISTRATION

89333-2 Vol 2

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OFCHEMICAL
SAFETY AND POLUTION
PREVENTION

January 30, 2015

I, Hope Johnson, Fungicide Branch, Registration Division, Office of Pesticide Programs, Office of Chemical Safety and Polution Prevention, United States Environmental Protection Agency ("EPA"), certify that the pesticide product (s) listed below is, as of the date of this letter, a registered product under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, and that as such, the product(s) may be sold and marketed in the United States of America as authorized and limited by FIFRA. A true and correct copy of the product label approved by EPA is attached to accompany this letter.

Registration of this product(s) with EPA also denotes that the registrant listed below is responsible for ensuring full compliance with all the laws of the United States of America, or governing jurisdiction, regarding the sale, storage and/or disposal of the product(s). Further, the recipient of this letter is on notice that the referenced registration and/or the accompanying label may change subsequent to the date of this letter. EPA assumes no responsibility to notify the recipient(s) (i.e., Lebanon) of this letter of any change in the status of the registration(s) and/or the product label for the product(s) listed below.

EPA has issued registration numbers for the product(s) listed below to:

Agria Canada, Inc.
207 Bank Street
Suite 464
Ottawa ON Canada K2P 2N2

EPA Registration Number: 89333-2
Name of Product: Mancozeb 80 WP Manufacturing Concentrate

Hope Johnson
Risk Manager 21
Fungicide Branch
Registration Division ()

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060

EPA

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[ ] Amendment
[X] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number
Agria Canada, Inc. 89333-2

2. EPA Product Manager
Hope Johnson

3. Proposed Classification
[X] None [ ] Restricted

4. Company/Product (Name)
Agria Canada / Mancozeb 80 WP Manufacturing Use Concentrate

PM# 21

5. Name and Address of Applicant *(Include ZIP Code)*
Agria Canada, Inc. 207 Bank St. Suite ~~442~~ 464
Ottawa ON Canada K2P 2N2

[ ] *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[ ] Final printed labels in response to Agency letter dated _____
[ ] "Me Too" Application.
[X] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Request 1 copiy Gold Seal certificate for 89333-2, 1 for use in Lebanon

Please send letters to D. O'Shaughnessy Consulting, 427 Hide Away Circle, Cub Run, KY 42729

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging
[ ] Yes*
[X] No
*** Certification must be submitted***

Unit Packaging
[ ] Yes
[X] No
If "Yes" Unit Packaging wgt. / No. per container

Water Soluble Packaging
[ ] Yes
[X] No
If "Yes" Package wgt / No. per container

2. Type of Container
[ ] Metal
[ ] Plastic
[ ] Glass
[ ] Paper
[X] Other (Specify) Foil-lined paper bag

3. Location of Net Contents Information
[ ] Label [X] Container

4. Size(s) Retail Container
2 Kg, 15 Kg, 25 Kg.

5. Location of Label Directions
[ ] On Label
[X] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product
[X] Lithograph
[ ] Paper glued
[ ] Stenciled
[ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Don O'Shaughnessy	Agent	(270) 524-5633

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

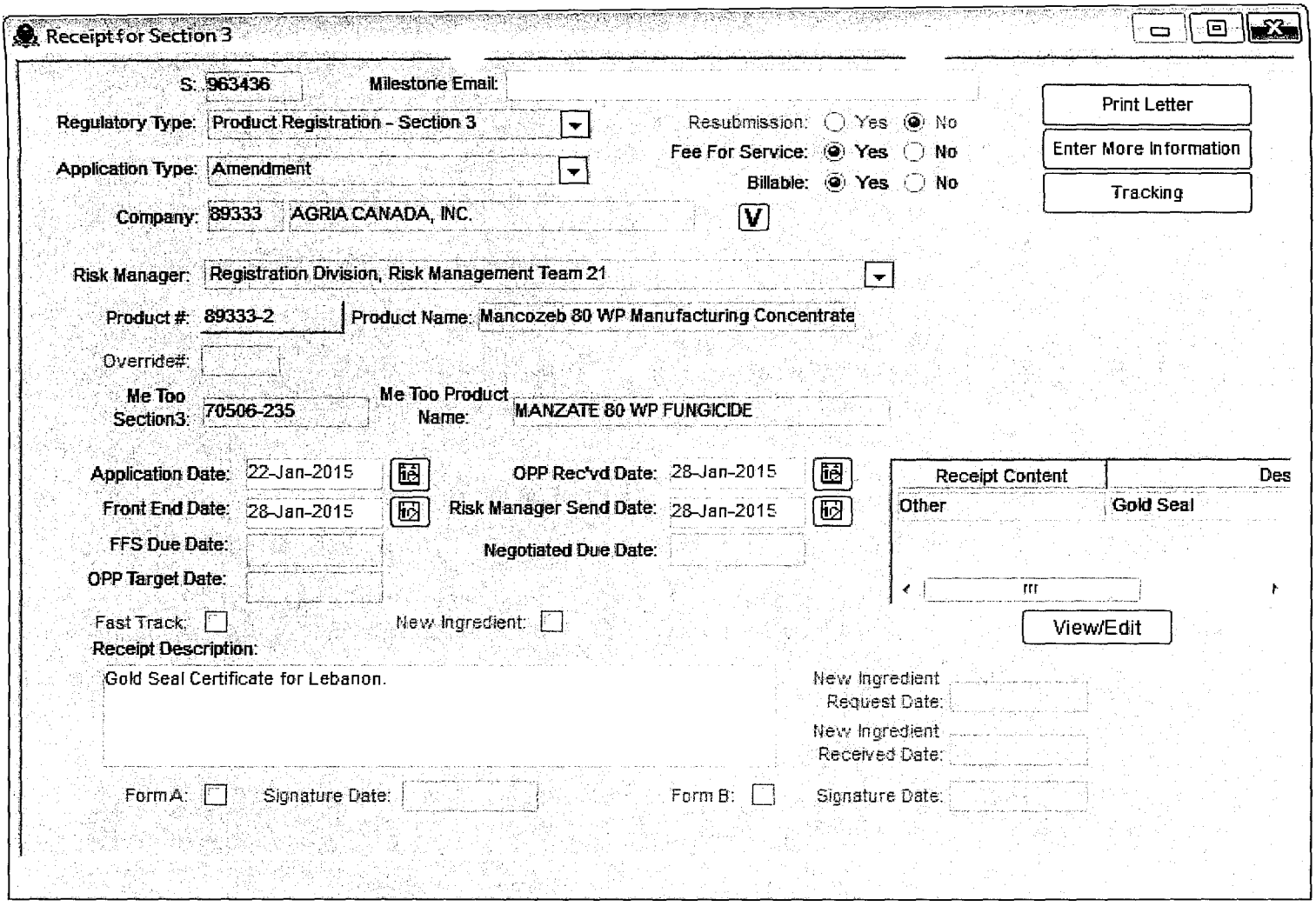
6. Date Application Received (Stamped)

2. Signature 

3. Title
Agent

4. Typed Name
Don O'Shaughnessy

5. Date
01/22/2014


Receipt for Section 3
S: 963436
Milestone Email:
Regulatory Type: Product Registration - Section 3
Application Type: Amendment
Company: 89333 AGRIA CANADA, INC.
Resubmission: Yes No
Fee For Service: Yes No
Billable: Yes No
Print Letter
Enter More Information
Tracking
Risk Manager: Registration Division, Risk Management Team 21
Product #: 89333-2
Product Name: Mancozeb 80 WP Manufacturing Concentrate
Override#:
Me Too Section3: 70506-235
Me Too Product Name: MANZATE 80 WP FUNGICIDE
Application Date: 22-Jan-2015
Front End Date: 28-Jan-2015
FFS Due Date:
OPP Target Date:
OPP Rec'vd Date: 28-Jan-2015
Risk Manager Send Date: 28-Jan-2015
Negotiated Due Date:
Receipt Content
Des
Other
Gold Seal
View/Edit
Fast Track:
New Ingredient:
Receipt Description:
Gold Seal Certificate for Lebanon.
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

January 28, 2015

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-499435
EPA File Symbol or Registration Number: 89333-2
Product Name: Mancozeb 80 WP Manufacturing Concentrate
EPA Receipt Date: 28-Jan-2015
EPA Company Number: 89333
Company Name: AGRIA CANADA, INC.

DON O'SHAUGHNESSY, PH.D
D. O'SHAUGHNESSY CONSULTING, INC.
AGRIA CANADA, INC.
427 HIDE AWAY CIRCLE
CUB RUN, KY 42729-

SUBJECT: Receipt of Request for Gold Seal Certification Letter(s)

Dear Registrant:

The Office of Pesticide Programs has received your request for Gold Seal Certification letter(s) that is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The action has been identified as action code M006:

UP TO 5 GOLD SEAL CERTIFICATION LETTERS PER REGISTRATION

No additional payment is due at this time. If you have any questions, please contact Betty Williams at (703) 308-0132.

Sincerely,

Front End Processing Staff
Information Technology & Resources Management Division

Commercial/financial information may be entitled to confidential treatment

2758

D. O'SHAUGHNESSY CONSULTING, INC.
427 HIDE AWAY CIRCLE
CUB RUN, KY 42729-8692
(270) 524-5633

73-36-839

DATE 1/26/2015

PAY TO THE ORDER OF — US-EPA — $ 526.00

—FIVE-HUNDRED-TWENTY-SIX-AND xx/100 DOLLARS

Security Features Included. Details on Back

usbank. All of us serving you®

FOR GOLD SEAL CERTS (2@ 263)

MP

⑈002758⑈ [redacted]

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

September 14, 2015

Don O'Shaughnessy
Agent for Agria Canada, Inc.
c/o D. O'Shaughnessy Consulting, Inc.
427 Hide Away Circle
Club Run, KY 42729

Subject: PRIA Review – Acute toxicity studies to support registration in place of previous citations.
Product Name: Mancozeb 80 WP Manufacturing Concentrate
EPA Reg. No.: 89333-2
Application Date: 07/07/2015
Decision Number: 507154

Dear Mr. O'Shaughnessy:

The acute toxicity studies submission referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, has been reviewed. Please see the attached review dated 08/19/2015.

If you have any questions, you may contact Maryam K. Muhammad at 703-347-0301 or via email at Muhammad.maryam@epa.gov.

Sincerely,

Hope Johnson, Product Manager 21
Fungicide Branch
Registration Division (7505P)
Office of Pesticide Programs

Enclosure

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

19/AUG/2015

MEMORANDUM: Acute Toxicity Review for Mancozeb 80 WP Manufacturing Concentrate

Subject:	Name of Pesticide Product:	Mancozeb 80 WP Manufacturing Concentrate
	EPA Reg. No.:	89333-2
	DP Barcode:	D428382
	Decision No.:	507154
	Action Code:	R340
		PC Codes: 014504 Mancozeb

From: Tracy Keigwin, Biologist
Chemistry, Inerts and Toxicology Assessment Branch
Registration Division (7505P)

Through: Masih Hashim, Ph.D.
Chemistry, Inerts and Toxicology Assessment Branch
Registration Division (7505P)

To: Maryam Muhammad
Fungicide Branch
Registration Division (7505P)

Applicant: Don O'Shaughnessy, Agent for Agri Canada Inc.
D. O'Shaughnessy Consulting, Inc.
427 Hide Away Circle
Cub Run, KY 42729-8692

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Mancozeb	80.0
Other Ingredient(s):	20.0
Total:	100.0%

ACTION REQUESTED: The Risk Manager requests a review of acute toxicity studies submitted in support of Mancozeb 80 WP Manufacturing Concentrate, EPA Reg. No. 89333-2.

BACKGROUND: Agri Canada Inc. has submitted product-specific acute toxicity data in support of Mancozeb 80 WP Manufacturing Concentrate, EPA Reg. No. 89333-2. The registrant has submitted the following acute toxicity data: MRIDs 49580302 (870.1100), 49580303 (870.1200), 49580304 (870.1300), 49580306 (870.2400), 49580305 (870.2500), and 49580307 (870.2600). The product label states that Mancozeb 80WP Manufacturing Concentrate is only for formulation into a fungicide for listed uses. Note that the test substance in the submitted studies is referred to as "Fortuna 800 WP". This is an alternative name for the subject product.

OF NOTE: EPA Reg. No. 89333-2 was originally cited to support the registration of EPA File Symbol 89333-U, a product containing 85% mancozeb. That citation was denied due to the lower concentration of mancozeb (80%) in EPA Reg. No. 89333-2 compared to the concentration of mancozeb (85%) in EPA File Symbol 89333-U. In response, the registrant has submitted product specific acute toxicity data for EPA Reg. No. 89333-2 and also for technical product 89333-3 (93.2% mancozeb; reviewed under DP Barcode 428381) in the hopes that the combined data from both products will be sufficient to support the registration of EPA File Symbol 89333-U and make additional animal testing unnecessary.

GLP: All studies were conducted in accordance with GLP.

DEFICIENCIES/DEVIATIONS: None

COMMENTS AND RECOMMENDATIONS:
1) Only 5 of the 6 product specific studies submitted in support of EPA Reg. No. 89333-2 are acceptable (see item #3, below). Note that the acute oral toxicity category has changed from Category IV to Category III. The new acute toxicity profile of Mancozeb 80 WP Manufacturing Concentrate, EPA File Symbol 89333-2 is as follows:

acute oral toxicity	III	Acceptable	MRID 49580302
acute dermal toxicity	III	Acceptable	MRID 49580303
acute inhalation toxicity	IV	Acceptable	MRID 49580304
primary eye irritation	III	Acceptable	MRID 49580306
primary skin irritation	IV	Acceptable	MRID 49580305
dermal sensitization	Negative	**Unacceptable**	MRID 49580307

2) The primary eye irritation study (MRID 49580306) was not conducted according to Health Effects Test Guideline 870.2400 but is still acceptable for regulatory purposes. The study states that the eyes of test subjects were rinsed for one minute at one hour post instillation because the test substance had not been removed from the eye by physiological means. Health Effects Test Guideline 870.2400 states that "the eyes of the test animals should not be washed out for 24 hours following instillation of the test substance." OECD Guideline 405 does allow a rinse for solid test substances at 1 hour if the test material is still present in the eye. In addition, the previous eye irritation classification for this product was also Category III. CITAB does not believe in this specific case that the classification for primary eye irritation would have been altered by the eye rinse and will accept this study for regulatory purposes.

3) The dermal sensitization study is unacceptable. The study author states "since the dose of 0.5 g (the highest concentration tested) did not cause any skin reaction this was chosen for both induction and challenge applications". Health Effects Test Guideline 870.2600 states "...in the Buehler test, select the concentration of the induction dose such that it is high enough to cause mild irritation, and the challenge dose such that it is the highest non-irritating concentration". A concentration higher than 0.5g should have been tested. In addition, a positive control study was not conducted concurrently nor the data of one conducted within 6 months of the study provided. This is a requirement and necessary to assess the sensitivity and reliability of the experimental technique. A new dermal sensitization study must be submitted or cited. Alternatively, this product can be labeled as a dermal sensitizer and have the corresponding precautionary language. CITAB notes that this product was previously labeled as a dermal sensitizer. In the event that the registrant chooses to label this product as a dermal sensitizer CITAB will provide the precautionary language for this product. If the registrant chooses to conduct or cite a different study please inform CITAB so that this review may be revised accordingly.

3) The following are the precautionary and first aid statements for this product (includes dermal sensitization precautionary language):

PRODUCT ID #: **89333-2**

PRODUCT NAME: **Mancozeb 80 WP Manufacturing Concentrate**

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals:

Harmful if swallowed. Harmful if absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse. Wear: *protective eyewear, long-sleeved shirt and long pants, socks, shoes, and chemical-resistant gloves.

Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

*Protective eyewear may be worn, if appropriate

First Aid:

If swallowed:
-Call a poison control center or doctor immediately for treatment advice.
-Have person sip a glass of water if able to swallow.
-Do not induce vomiting unless told to by a poison control center or doctor.
-Do not give anything to an unconscious person.

If on skin:
-Take off contaminated clothing.
-Rinse skin immediately with plenty of water for 15-20 minutes.
-Call a poison control center or doctor for treatment advice.

If in eyes:
-Hold eye open and rinse slowly and gently with water for 15-20 minutes.
-Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
-Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

Reviewer: *Tracy Keigwin* **Date:** August 19, 2015
Risk Manager (EPA): 21

The following table is the Acute Toxicity Data Evaluation Record (DER) for the six studies submitted in support of EPA Reg. No. 89333-2:

1. DP BARCODE: 428382				
2. PC CODES: 014504				
3. CURRENT DATE: August 19, 2015				
4. TEST MATERIAL: Fortuna 800 WP (Batch # 135; Purity: 794.4 g/Kg; solid; pH = 6.55)				
Study/Species/Lab Study # /Date	**MRID**	**Results**	**Tox Cat**	**Core Grade**
Acute oral toxicity/rat BIOAGRI Laboratorios (Planaltina, Brazil) Study #A0317.305.369.06/ March 14, 2007 OCSPP 870.1100; OECD 425	49580302	LD_{50} Females > 2000 mg/kg bw (2 groups of 3 females tested). At 2000 mg/kg all survived. No clinical signs observed. No gross abnormalities observed at necropsy	III	A
Acute dermal toxicity/rat BIOAGRI Laboratorios (Planaltina, Brazil) Study #A0317.310.350.06/ March 14, 2007 OCSPP 870.1200; OECD 402	49580303	LD_{50} > 2000 mg/kg bw (both sexes and combined). All test subjects (5/5 males and 5/5 females) survived. No clinical signs observed. No gross abnormalities observed at necropsy.	III	A
Acute inhalation toxicity/rat BIOAGRI Laboratorios (Planaltina, Brazil) Study #A0317.309.278.06/ March 14, 2007 OCSPP 870.1300; OECD 403	49580304	LC_{50} > 2.885 mg/L (Nose-only, gravimetrically determined; both sexes and combined). Mean MMAD and GSD: 3.319 µm and 2.123, respectively. All survived. No clinical signs observed. No gross abnormalities observed at necropsy.	IV	A
Primary eye irritation/rabbit BIOAGRI Laboratorios (Planaltina, Brazil) Study #A0317.312.465.06/ March 14, 2007 OCSPP 870.2400; OECD 405	49580306	One animal (1/3) vocalized after test substance application. No corneal opacity or iritis observed. Grade 2 redness and/or chemosis was observed in 1/3 rabbits at the one hour observation increasing to 3/3 at the 24 hour observation. All scores "0" by the 72 hour observation.	III	A
Primary dermal irritation/ rabbit BIOAGRI Laboratorios (Planaltina, Brazil)	49580305	PDI = 0. No erythema or edema observed.	IV	A

Study #A0317.311.368.06/ March 14, 2007 OCSPP 870.2500; OECD 404				
Dermal sensitization (Buehler)/Guinea Pig BIOAGRI Laboratorios (Planaltina, Brazil) Study #A0317.318.327.06/ March 14, 2007 OCSPP 870.2600; OECD 406	49580307	Product is not a dermal sensitizer. Based on preliminary screening a 0.500 g concentration was selected for both the induction and challenge phases. No positive responses (grade 1 or higher) were observed in test animals either at the 24 hour or 48 hour challenge observations. No positive responses (grade 1 or higher) were observed in naïve control animals at 24 or 48 hours. This study is unacceptable. Please see item #3 in comments and recommendations for complete details.	Negative	**U**

Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, D = Data Gap

Muhammad, Maryam K.

From: Muhammad, Maryam K.
Sent: Monday, September 14, 2015 3:43 PM
To: 'Don O'Shaughnessy'; 'Don O'Shaughnessy'
Subject: EPA REG. NOs. 89333-2 and -3 Suggested Label Revisions to accompany next label amendment submission
Attachments: 89333-2-20150406 mm-ToxUpdate hj.pdf; 89333-3-20150615 mmToxUpdate hj.pdf

Dear Mr. O'Shaughnessy:

The Agency suggests that you update your labels for your next label amendment submission for the following products: 89333-2 and 89333-3

Please see attached label with comments.

If you have questions concerning this letter, please contact me at 703-347-0301 or via email at Muhammad.maryam@epa.gov.

Thank your for your time.

Regards,

MARYAM K. MUHAMMAD | BIOLOGIST | REGISTRATION DIVISION | *U.S. EPA, OFFICE OF PESTICIDE PROGRAMS* | *PHONE: 703.347.0301*

doc
D. O'Shaughnessy Consulting, Inc.

Aug. 22, 2015 PM 21

Ms. Heather Garvie (PM 24)
US EPA, RD (7504P)
Rm. S-4900, One Potomac Yard
2777 Crystal Drive
Arlington, VA 22202-4501

Dear Ms. Garvie,
RE: Supplemental data, application to register Mancozeb 85 WP Manufacturing Concentrate on behalf of Agria Canada, Inc. (89333-U)

Enclosed is a CD with a response to the email from Maryam Muhammad, Aug. 11, 2015. (text attached):
Hi Mr. O'Shaughnessy,
I hope all is well.
Thank you for submitting the revised studies with the missing page numbers. Our science division is reviewing these studies.
I just wanted to remind you that your dermal sensitization study is still missing a positive control and must be resubmitted in order to complete the review.
Please let me know the status of our request.
Best Regards,
***Maryam K. Muhammad** |Biologist | Registration division | U.S. EPA, Office of Pesticide Programs | Phone: 703.347.0301*

Specifically, The CD has on it the positive control data from BioAgri from the time period related to the sensitization data submitted. This positive control study will support the pending application for 89333-U, as well as Mancozeb Technical (89333-3) and 80% Manufacturing Concentrate (89333-2). Accordingly, I also enclose updated Matrices for these latter 2 products as hard copy.

As always, thank you for your attention to this so far, and if you require any further action, please contact me at the co-ordinates on this letterhead or at my cell # (270-537-5139).

Sincerely,

Don O'Shaughnessy, Ph.D., DABT

427 Hide Away Circle, Cub Run, KY 42729 207 Bank St., Ste. 412, Ottawa, ON CANADA K2P 2N2

Phone 270-524-5633 cell 270-537-5139 email doctox@mac.com www.regtox.net

TRANSMITTAL DOCUMENT

1. Name and Address of Submitter

D. O'Shaughnessy Consulting, Inc., 427 Hide Away Circle, Cub Run, KY 42729

for

Agria Canada, Inc.

2. Regulatory Action in Support of Which This Package is Submitted

Application to register Mancozeb 85 WP Manufacturing Use Concentrate containing mancozeb

3. Transmittal Date

Aug 19, 2015

4. List of Submitted Materials (e-submission on DVD)

Volume 1 of 4: Administrative materials (Cover letter, this Document, updated data matrix)

Volume 2 of 2: Positive Control Data for Guinea Pig Sensitization, BioAgri Labs, 2006 **MRID 49580308**

Transmitted by: Don O'Shaughnessy, Ph.D., DABT, DABFM

Contact Information: tel. 270.524.5633 / cell 270-537-5139
fax 270.524.5634
email doctoc@mac.com

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 7-8-15

Experts In-Processing Signature: B.B. Date 7-23-15 Fee Paid: Yes ✓

Division management contacted on issues No_____ Yes_____ Date_____

EPA Reg. Number: 89333-2	EPA Receipt Date: 7-8-15

	Items for Review			Yes	No	N/A*
1	**Application Form** (EPA Form 8570-1) signed & complete including package type			X		
2	**Confidential Statement of Formula** all boxes completed, form signed, and dated (EPA Form 8570-4)					X
	a) All inerts, including fragrances, approved for the proposed uses (see Footnote A)	**yes**	**no**			
3	**Certification with Respect to Citation of Data** (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent					
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	**yes**	**no**			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	**Formulator's Exemption Statement** (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
5	**Data Matrix** (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
		yes	**no**			
	a) Selective Method (Fee category experts use)	X				
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	**5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)**					X
7	**Is the data package consistent with PR Notice 86-5**			X		
8	**Notice of Filing included with petitions**					X

9	**If applicable for conventional applications, <u>reduced risk rationale</u>**			K
	<u>Required Data</u> and/or data waivers. See Footnote C.			
10	a) List study (or studies) not included with application			

Comments:

Documentation: Pass

- Required forms

Inerts: N/A

- No inerts to review.

II-3: (Fail)

MRID - 495803

- Studies were completed in April and partially accepted.

Status: (Fail) IU 7/30/15

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the inert Web site and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch.

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or

3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

Jackson, Tracy

From: Jackson, Tracy
Sent: Tuesday, July 28, 2015 1:44 PM
To: 'doctox@mac.com'
Subject: Application Reg# 89333-2 and 89333-3

Dear Dr. O'Shaugnessy,

I am contacting you regarding your submission in support of **Mancozeb 80WP Manufacturing Concentrate (89333-2)** and **Mancozeb Technical (89333-3)**. A Certification with Respect to Citation of Data is required with this submission, because a data matrix is present.

Please send form for both registrations to jackson.tracy@epa.gov

Thank You

Tracy Jackson
EPA Contractor
703-308-7227
2777 S. Crystal Drive
Arlington, VA 22202

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

July 22, 2015

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-507154
EPA File Symbol or Registration Number: 89333-2
Product Name: Mancozeb 80 WP Manufacturing Concentrate
EPA Receipt Date: 08-Jul-2015
EPA Company Number: 89333
Company Name: AGRIA CANADA, INC.

DON O'SHAUGHNESSY, PH.D
D. O'SHAUGHNESSY CONSULTING, INC.
AGENT FOR AGRIA CANADA, INC.
427 HIDE AWAY CIRCLE
CUB RUN, KY 42729-

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R340

AMENDMENT;NON-FAST TRACK;REVIEW WITHIN RD, E.G. PRECAUTIONARY LABELING;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service {971024w~

This package includes the following

- ○ New Registration
- ◉ Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ___

for Division

- ○ AD
- ○ BPPD
- ◉ RD

Risk Mgr. 21

Receipt No. S-	971024
EPA File Symbol/Reg. No.	89333-2
Pin-Punch Date:	7/8/2015

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R340

Granted: R340

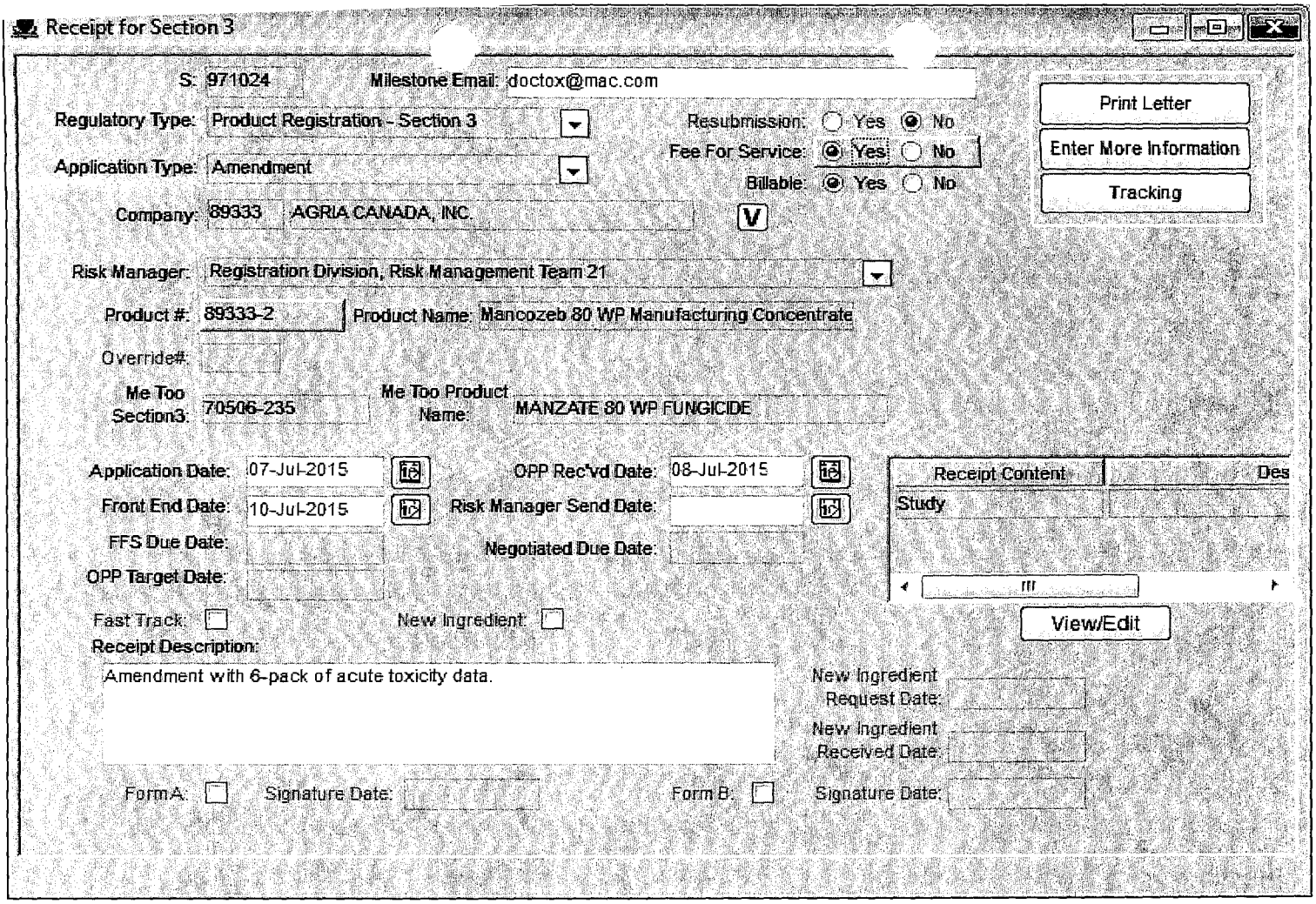
Amount Due: $ 3798

Parent/Child Decisions:

☒ Inert Cleared for Intended Use ☒ Uncleared Inert in Product

Reviewer: per Steve Schaible (See email) Date: 7/10/15

Remarks:


Receipt for Section 3
S: 971024
Milestone Email: doctox@mac.com
Regulatory Type: Product Registration - Section 3
Application Type: Amendment
Company: 89333 AGRIA CANADA, INC.
Resubmission: Yes No
Fee For Service: Yes No
Billable: Yes No
Print Letter
Enter More Information
Tracking
Risk Manager: Registration Division, Risk Management Team 21
Product #: 89333-2
Product Name: Mancozeb 80 WP Manufacturing Concentrate
Override#:
Me Too Section3: 70506-235
Me Too Product Name: MANZATE 80 WP FUNGICIDE
Application Date: 07-Jul-2015
OPP Rec'vd Date: 08-Jul-2015
Front End Date: 10-Jul-2015
Risk Manager Send Date:
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Des
Study
Fast Track:
New Ingredient:
View/Edit
Receipt Description:
Amendment with 6-pack of acute toxicity data.
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

Yanchulis, Michael

From: Don O'Shaughnessy <doctox@mac.com>
Sent: Wednesday, July 22, 2015 12:00 PM
To: Yanchulis, Michael
Subject: Fwd: Pay.gov Payment Confirmation: PRIA Service Fees

Don O'Shaughnessy, Ph.D., DABT, DABFM
President, DOC Inc.
427 Hide Away Circle
Cub Run KY 42729
270-524-5633 cell 270-537-5139
doctox@mac.com
www.regtox.net

Begin forwarded message:

From: notification@pay.gov
Subject: Pay.gov Payment Confirmation: PRIA Service Fees
Date: July 22, 2015 at 10:48:26 AM CDT
To: doctox@mac.com

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or yanchulis.michael@epa.gov.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 25MFR76K
Agency Tracking ID: 74843018096
Transaction Type: Sale
Transaction Date: 07/22/2015 11:48:25 AM EDT

Account Holder Name: Don O'Shaughnessy

Transaction Amount: $3,798.00
Billing Address: 427 Hide Away Circle
Billing Address 2:
City: Cub Run
State/Province: KY
Zip/Postal Code: 42729
Country: USA

Yanchulis, Michael

From: Schaible, Stephen
Sent: Friday, July 10, 2015 1:11 PM
To: Don O'Shaughnessy; Johnson, Hope
Cc: Giles-Parker, Cynthia; Muhammad, Maryam K.; Downs, Teresa; Yanchulis, Michael
Subject: RE: 89333-U; acute toxicity data submitted in support of this pending product

Hi Don,

These two applications for EPA Registration Numbers 89333-2 and 89333-3 should have been submitted to the Front End Document Processing Center identified as PRIA applications (each one being an R340) with proof of payment for each. Because they were not identified as PRIA in the cover letter, they were sent upstairs to the PM to which they were addressed. All of that being said, I have spoken with Mick Yanchulis in our Information Services Branch and he will process these as if they had come as PRIA and will invoice you for the two outstanding R340 payments. You should get that email today or Monday, and the PRIA clock on these will start 21-days from the receipt of payment.

These two R340 actions (reviewing the two sets of acute toxicity studies, evaluating whether label changes to the product labels would be required based on these data) will be evaluated separately from the new product application that was previously submitted for EPA File Symbol 89333-U, but the results of those reviews will inform the waiver-type argument that you are making with regard to new product application (that given the acute toxicity characteristics of the active ingredient in question, one should be able to cite data reflecting a different % a.i. to support the proposed new product).

Have a great weekend!

Best regards, Steve

Stephen A. Schaible, PRIA Ombudsman
Registration Division (7505P)
Office of Pesticide Programs
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460
ph: (703)308-9362

From: Don O'Shaughnessy [mailto:doctox@mac.com]
Sent: Wednesday, July 08, 2015 11:04 AM
To: Johnson, Hope
Cc: Giles-Parker, Cynthia; Schaible, Stephen; Muhammad, Maryam K.; Downs, Teresa
Subject: Re: 89333-U; acute toxicity data submitted in support of this pending product

Sent yesterday by UPS - should be at your mailroom today.

Johnson, Hope

From: Johnson, Hope
Sent: Thursday, July 09, 2015 12:41 PM
To: Schaible, Stephen
Cc: Muhammad, Maryam K.; Giles-Parker, Cynthia
Subject: FW: 89333-U; acute toxicity data submitted in support of this pending product
Attachments: applicmancotechacutetox7-7-15.pdf; ATT00001.htm; matrixmanco80WPjuly7-15.pdf; ATT00002.htm; matrixmancotechjuly7-15.pdf; ATT00003.htm; applic80WPacutetox7-7-15.pdf; ATT00004.htm

He sent these in regular correspondence without payment stating "I am uncertain what the PRIA fee implication would be given the fee included with the original submission of 89333-U. I trust you will advise on how this impacts on fee, at which time I can deal with this through "pay.gov"

Steve- can you respond directly to him regarding these being sent to be coded 2 separate R340 actions and the fee and timeframes associated? Can you get these coded? I can drop them off to you.

Thanks,
Hope

From: Don O'Shaughnessy [mailto:doctox@mac.com]
Sent: Wednesday, July 08, 2015 11:04 AM
To: Johnson, Hope
Cc: Giles-Parker, Cynthia; Schaible, Stephen; Muhammad, Maryam K.; Downs, Teresa
Subject: Re: 89333-U; acute toxicity data submitted in support of this pending product

Sent yesterday by UPS - should be at your mailroom today.

doc
D. O'Shaughnessy Consulting, Inc.

July 7, 2015

Ms. Hope Johnson (PM 21)
US EPA, RD (7504P)
Rm. S-4900, One Potomac Yard
2777 Crystal Drive
Arlington, VA 22202-4501

Dear Ms. Johnson,
RE: Revised data matrices 89333-2, 89333-3 per your email of June 29, 2015 (regarding 89333-U, Decision No. 499556)

Enclosed is a response to the subject email (text attached):
The Agency has begun review of your resubmissions dated March 8, 2015, June 4, 2015 and June 9, 2015 for EPA File Symbol No. 89333-U; Decision Number 499556. You have submitted 2 sets of new 6-pack acute toxicity data not previously reviewed by the Agency, which support EPA Registration Numbers 89333-3 and 89333-2, and a bridging argument to satisfy the acute toxicity data requirements for –U based on these data.
We find it more appropriate that each new 6-pack of acute toxicity data be submitted as a R340 PRIA action under the corresponding Registration the data supports (either 89333-3 or 89333-2). The data you submitted could result in revised acute toxicity categories for 89333-3 and/or 89333-2 if the Agency review of this data results in categories that differ from the previously cited data for the respective products. Once the data is reviewed under each separate Registration Number, the Agency can then review the bridging argument for your pending R310 PRIA action (89333-U) and refer to the separate Agency reviews for -2 and -3.
Please note that the new studies, once reviewed, may require label changes regarding Precautionary or First Aid Statements for -2 or -3 if the acute toxicity categories differ from the previously cited data.
Please respond with your proposed course of action regarding 89333–U, -2 and -3 by Wednesday July 8, 2015.

Agria Canada hereby submits revised matrices for 89333-2 and 8933-3. According to my evaluation of the label review manual and the acute toxicity data, no label changes appear to be required. In absence of any response to my query about re-submitting these data under new MRIDs, I have taken the position that it is less confusing to simply refer to the MRIDs of the studies already submitted March 8, 2015 (copy of that transmittal document is enclosed).

I am uncertain what the PRIA fee implication would be given the fee included with the original submission of 89333-U. I trust you will advise on how this impacts on fee, at which time I can deal with this through "pay.gov".

As always, thank you for your attention to this so far, and if you require any further action, please contact me at the co-ordinates on this letterhead or at my cell # (270-537-5139).

Sincerely,

Don O'Shaughnessy, Ph.D., DABT

427 Hide Away Circle, Cub Run, KY 42729 207 Bank St., Ste. 412, Ottawa, ON CANADA K2P 2N2

Phone 270-524-5633 cell 270-537-5139 email doctox@mac.com www.regtox.net

TRANSMITTAL DOCUMENT

1. Name and Address of Submitter

D. O'Shaughnessy Consulting, Inc., 427 Hide Away Circle, Cub Run, KY 42729

for

Agria Canada, Inc.

2. Regulatory Action in Support of Which This Package is Submitted

Application to register Mancozeb 85 WP Manufacturing Use Concentrate containing mancozeb

3. Transmittal Date

March8, 2015

4. List of Submitted Materials (e-submission on DVD)

Volume 1 of 14: Administrative materials (Cover letter, this Document, data matrix)

Volume 2 of 14 : Rationale to rely on acute toxicity data for 80% WP + mancozeb technical in support of 85% WP MRID 49580301

Volume 3 of 14: Acute oral toxicity, Mancozeb 80 WP MRID 49580302

Volume 4 of 14: Acute dermal toxicity, Mancozeb 80 WP MRID 49580303

Volume 5 of 14: Acute inhalation toxicity, Mancozeb 80 WP MRID 49580304

Volume 6 of 14: Dermal irritation, Mancozeb 80 WP MRID 49580305

Volume 7 of 14: Eye irritation, Mancozeb 80 WP MRID 49580306

Volume 8 of 14: Sensitization, Mancozeb 80 WP MRID 49580307

Volume 9 of 14: Acute oral toxicity, Mancozeb technical MRID 49580308

Volume 10 of 14: Acute dermal toxicity, Mancozeb technical MRID 49580309

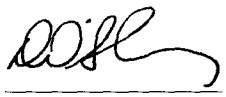
Volume 11 of 14: Acute inhalation toxicity, Mancozeb technical MRID 49580310

Volume 12 of 14: Dermal irritation, Mancozeb technical MRID 49580312

Volume 13 of 14: Eye irritation, Mancozeb technical MRID 49580311

Volume 14 of 14: Sensitization, Mancozeb technical MRID 49580313

Transmitted by: Don O'Shaughnessy, Ph.D., DABT, DABFM



Contact Information: tel. 270.524.5633 / cell 270-537-5139
fax 270.524.5634
email doctox@mac.com

Please read instructions on reverse before compl[e] form. Form Approved. [O]B No. 2070-0060

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[ ] Amendment
[X] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number: 89333-2

2. EPA Product Manager: Hope Johnson

3. Proposed Classification: [X] None [ ] Restricted

4. Company/Product (Name): Agria Canada, Inc. / Mancozeb 80 WP Manufacturing Concentrate

PM# 21

5. Name and Address of Applicant *(Include ZIP Code)*
Agria Canada, Inc.,
207 Bank St., Suite 412
Ottawa ON Canada K2P 2N2

[ ] *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[ ] Final printed labels in response to Agency letter dated _____
[ ] "Me Too" Application.
[X] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
Change of support for acute toxicity data requirements from "cite all" to "OWN", with reference to data submitted March 8, 2015 for 89333-U

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [X] No	[ ] Yes [X] No	[ ] Yes [X] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [X] Other (Specify) foil and poly-lined paper bag
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information: [X] Label [ ] Container

4. Size(s) Retail Container: 30 lb, 50 lb

5. Location of Label Directions: [X] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product: [X] Lithograph / Paper glued / Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Don O'Shaughnessy	Agent	270-524-5633

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature: [signature]

3. Title: Agent

4. Typed Name: Don O'Shaughnessy

5. Date: July 7, 2015

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.
Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number	EPA Registration Number/File Symbol
Agria Canada, Inc..	89333-2
Active Ingredient(s) and/or representative test compound(s) mancozeb	Date 07/28/2015
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) outdoor food, non-food	Product Name Mancozeb 80 WP Manufacturing Concentrate

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☑ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

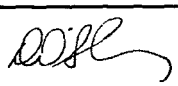
I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
	07/28/2015	Don O'Shaughnessy, Agent

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.

Based on Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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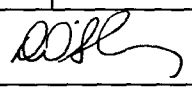
DATA MATRIX

Date 08/19/2015			EPA Reg. No./File Symbol 89333-2		Page 1 of 7
Applicant's/Registrant's Name & Address Agria Canada, Inc., 207 Bank St., Suite 412 Ottawa ON Canada K2P 2N2			Product Mancozeb 80 WP Manufacturing Concentrate		
Ingredients mancozeb					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product Identity and Composition	(CSF) 48868800	Agria Canada, Inc.	OWN	
830.1600	Description of Materials Used to Produce the Product	48868801	Agria Canada, Inc.	OWN	
830.1620	Description of Manufacturing Process	48868801	Agria Canada, Inc.	OWN	
830.1670	Discussion of Formation of Impurities	48868801	Agria Canada, Inc.	OWN	
830.1750	Certified Limits	48868801	Agria Canada, Inc.	OWN	
830.1800	Enforcement analytical method	48868803	Agromarketing Inc.	OWN	
830.6303	Physical State	48868802	Agria Canada, Inc.	OWN	
830.6304	Odor	48868802	Agria Canada, Inc.	OWN	
830.7300	Density	48868802	Agria Canada, Inc.	OWN	
830.6302	Color	48868802	Agria Canada, Inc.	OWN	
830.6315	Flammability	48868802	Agria Canada, Inc.	OWN	
830-6314	Oxidation / reduction	48868802	Agria Canada, Inc.	OWN	
830.6317 / 6320	Storage Stability / corrosion characteristics	48868803	Agria Canada, Inc.	OWN	
830.1800	Enforcement analytical method (additional)	48993801	Agria Canada, Inc. Inc.	OWN	

Signature		Name and Title	Date
		Don O'Shaughnessy, Agent	08/19/2015

Based on Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date 08/19/2015			EPA Reg. No./File Symbol 89333-2		Page 2 of 7
Applicant's/Registrant's Name & Address Agria Canada, Inc., 207 Bank St., Suite 412 Ottawa ON Canada K2P 2N2			Product Mancozeb 80 WP Manufacturing Concentrate		
Ingredients mancozeb					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1100	acute oral toxicicty	49580302	Agria Canada, Inc.	OWN	
870.1200	acute dermal toxicity	49580303	Agria Canada, Inc.	OWN	
870.1300	acute inhalation toxicity	49580304	Agria Canada, Inc.	OWN	
870.2400	acute eye irritation	49580306	Agria Canada, Inc.	OWN	
870.2500	acute dermal irritation	49580305	Agria Canada, Inc.	OWN	
870.2600	sensitization	49580307	Agria Canada, Inc.	OWN	
870.2600	Sensitization - positive control	49580308	Agria Canada, Inc.	OWN	1
all other genericdata		cite all		PAY	1
NA	rationale for use of 80 WP data for 85% WP	49580301	Agria Canada, Inc.	OWN	
Signature			Name and Title Don O'Shaughnessy, Agent		Date 08/19/2015

Based on Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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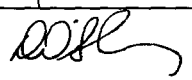
DATA MATRIX

Date 08/19/2015			EPA Reg. No./File Symbol 89333-2		Page 3 of 7
Applicant's/Registrant's Name & Address Agria Canada, Inc., 207 Bank St., Suite 412 Ottawa ON Canada K2P 2N2			Product Mancozeb 80 WP Manufacturing Concentrate		
Ingredients mancozeb					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product Identity and Composition	(CSF) 48449100	Agromarketing Company, Inc.	OWN	2
830.1600	Description of Materials Used to Produce the Product	48449101	Agromarketing Company, Inc.	OWN	2
830.1620	Description of Manufacturing Process	48449101	Agromarketing Company, Inc.	OWN	2
830.1670	Discussion of Formation of Impurities	48449101	Agromarketing Company, Inc.	OWN	2
830.1750	Certified Limits	48229200	Agromarketing Company, Inc.	OWN	2
830.1800	Enforcement analytical method	48449102	Agromarketing Company, Inc.	OWN	2
830.6303	Physical State	48449103	Agromarketing Company, Inc.	OWN	2
830.6304	Odor	48449103	Agromarketing Company, Inc.	OWN	2
830.6317 / 6320	Storage Stability / corrosion characteristics	489922501	Agromarketing Company, Inc.	OWN	2
830.7300	Density	48449103	Agromarketing Company, Inc.	OWN	2
830.6302	Color	48449103	Agromarketing Company, Inc.	OWN	2
830.7000	pH	48449103	Agromarketing Company, Inc.	OWN	2
830.7200	Melting point	48449103	Agromarketing Company, Inc.	OWN	2
830.7220	Boiling point	48449103	Agromarketing Company, Inc.	OWN	2
830.6315	Flammability	48449103	Agromarketing Company, Inc.	OWN	2
Signature 			Name and Title Don O'Shaughnessy, Agent		Date 08/19/2015

Based on Form Approved OMB No. 2070-0060

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401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date 08/19/2015			EPA Reg. No./File Symbol 89333-2		Page 4 of 7
Applicant's/Registrant's Name & Address Agria Canada, Inc., 207 Bank St., Suite 412 Ottawa ON Canada K2P 2N2			Product Mancozeb 80 WP Manufacturing Concentrate		
Ingredients mancozeb					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6316	Explosivity	48449103	Agromarketing Company, Inc.	OWN	2
830.6313	Stability to normal and elevated temperatures/ metal/	cite all		PAY	2
830.1700	Preliminary Analysis	48449102	Agromarketing Company, Inc.	OWN	2
Signature			Name and Title Don O'Shaughnessy, Agent		Date 08/19/2015

DATA MATRIX FOOTNOTES		
Date 08/19/2015	EPA Reg. No./File Symbol 89333-2	Page 5 of 7
Applicant's/Registrant's Name & Address Agria Canada, Inc., 207 Bank St., Suite 412 Ottawa ON Canada K2P 2N2	Product Mancozeb 80 WP Manufacturing Concentrate	

Footnote 1: A list of data submitters sent an offer to pay has been attached (following page)

Footnote 2: These data were submitted by Agromarketing Company to support Mancozeb Technical Fungicide 87845-4, transferred to Agria Canada as 89333-3 Dec. 3, 2012

Signature		Name and Title	Date
		Don O'Shaughnessy, Agent	08/19/2015

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FIFRA ENDANGERED SPECIES TASK FORCE, LLP
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Applicant's/Registrant's Name & Address Agria Canada, Inc., 207 Bank St., Suite 412 Ottawa ON Canada K2P 2N2			Product Mancozeb 80 WP Manufacturing Concentrate		
Ingredients mancozeb					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			Agria Canada, Inc.	OWN	
			Agria Canada, Inc.	OWN	
			Agria Canada, Inc.	OWN	
			Agria Canada, Inc.	OWN	
			Agria Canada, Inc.	OWN	
			Agromarketing Inc.	OWN	
			Agria Canada, Inc.	OWN	
			Agria Canada, Inc.	OWN	
			Agria Canada, Inc.	OWN	
			Agria Canada, Inc.	OWN	
			Agria Canada, Inc.	OWN	
			Agria Canada, Inc.	OWN	
			Agria Canada, Inc.	OWN	
			Agria Canada, Inc.	OWN	
Signature			Name and Title Don O'Shaughnessy, Agent		Date 08/19/2015

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			Agria Canada, Inc.	OWN	
			Agria Canada, Inc.	OWN	
			Agria Canada, Inc.	OWN	
			Agria Canada, Inc.	OWN	
			Agria Canada, Inc.	OWN	
				PAY	1
			Agria Canada, Inc.	OWN	
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Ingredients mancozeb					
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[redacted]			Agromarketing Company, Inc.	OWN	2
			Agromarketing Company, Inc.	OWN	2
			Agromarketing Company, Inc.	OWN	2
			Agromarketing Company, Inc.	OWN	2
			Agromarketing Company, Inc.	OWN	2
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				PAY	2
			Agromarketing Company, Inc.	OWN	2
				PAY	1
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		Don O'Shaughnessy, Agent	08/19/2015

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

April 6, 2015

Dr. Don O'Shaughnessy
Agent for Agri Canada, Inc.
D. O'Shaughnessy Consulting, Inc.
427 Hide Away Circle
Cub Run, KY 42729-8692

Subject: Label Amendment – Adding me-too use on walnut
Product Name: Mancozeb 80 WP Manufacturing Concentrate
EPA Registration Number: 89333-2
Application Date: 8/20/2014; resubmission dated 3/26/2015
Decision Number: 494961

Dear Dr. O'Shaughnessy:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Tamue Gibson by phone at (703) 305-9096 or via email at gibson.tamue@epa.gov.

Mancozeb 80 WP Manufacturing Concentrate

A Fungicide for Formulating Use.

ACTIVE INGREDIENT:
Mancozeb (a coordination product of zinc ion and manganese ethylenebisdithiocarbamate) . . . . . 80 %
(in which the ingredients are:
Manganese++ . . . . . 15.95 %
Zinc++ . . . . . 1.95 %
Ethylenebisdithiocarbamate ion ($C_4H_6N_2S_4$) . . . 62.10 %)

OTHER INGREDIENTS 20%
TOTAL: . . . . . 100.0 %

ACCEPTED
04/06/2015
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under
EPA Reg. No. 89333-2

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID

IF SWALLOWED: • Call poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING: • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15 to 20 minutes. • Call a poison control center or doctor for treatment advice.
IF IN EYES: • Hold eye open and rinse slowly and gently with water or 15 to 20 minutes. • Remove contact lenses, if present, after the first minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF INHALED: • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), call the National Pesticide Information Center at 1-800-858-7378.
This product contains mancozeb and ETU, chemicals known to the State of California to cause cancer. ETU is also known to the State of California to cause birth defects or other reproductive harm.

EPA Reg. No. 89333 - 2

EPA Est. No. 88475-BGR-1 Net Contents _____ Batch No. _____

Produced for: Agria Canada, Inc.133 Mavety St., Toronto, Ont. Canada M6P 2L8

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

PESTICIDE STORAGE: Store in original container in a dry area. Keep away from sources of ignition, (e.g. sparks and open flame.) Close bag when not in use. Do not store in a manner where cross-contamination with other pesticides, fertilizers, food or feed could occur. If spilled during storage or handling, sweep up spillage and dispose of in accordance with the Pesticide Disposal Instructions listed below.
PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.
CONTAINER DISPOSAL: Non-refillable container. No not reuse or refill this container. Completely empty bag into application equipment. Non-recyclable container. Dispose of empty bag in a sanitary landfill, or by incineration, or if allowed by State and Local authorities, by burning. If burned, stay out of smoke.

WARRANTY AND CONDITIONS OF SALE

Agria Canada warrants only that the material contained herein conforms to the chemical description on the label and is reasonably fit for use therein described when used in accordance with the Directions for Use set forth in the label.

To the extent consistent with applicable law, any damage arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages, such as loss of profits or values or any other special or indirect damages.
Agria Canada makes no other express or implied warranty including any other express or implied warranty of FITNESS or MERCHANTABILITY.

If you do not agree with or do not accept any of directions for use, the warranty disclaimers, or limitations
on liability, do not use the product, and return it unopened to the Seller, and the purchase price will be
refunded.

The sale of this product does not include a license under any patent owned by **Agria SA.**

Gibson, Tamue

From: Don O'Shaughnessy <doctox@me.com>
Sent: Thursday, March 26, 2015 10:34 AM
To: Gibson, Tamue
Subject: Re: EPA Registration Numbers: 89333-2 and 89333-3 Please revise the data matrices
Attachments: matrixmancotechMar26-15.pdf; ATT00001.htm; matrixmanco80WP03-26-15.pdf; ATT00002.htm

One day later than anticipated, but back in the office.
Here you go.

FOR OFFICIAL USE ONLY

FILE SYMBOL	
REGISTRATION NO.	89333-E

CONFIDENTIAL STATEMENT OF FORMULA ENCLOSED

DATE SUBMITTED	SUBMITTED BY (✓)	
	APPLICANT	BASIC SUPPLIER
JUL 12 2012		

Do Not Write Comments, Formula, or Parts of Formula on This Envelope

NOTE

It shall be unlawful—for any person to use for his own advantage or to reveal, other than to the Secretary, or officials or employees of the United States Department of Agriculture or other Federal agencies, or to the courts in response to a subpoena, or to physicians, and in emergencies to pharmacists and other qualified persons, for use in the preparation of antidotes, in accordance with such directions as the Secretary may prescribe, any information relative to formulas of products acquired by authority of Section 4 of the "Federal Insecticide, Fungicide, and Rodenticide Act."

Pages 53-54 Confidential Statement of Formula may be entitled to confidential treatment